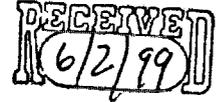




65434

1206 '99 JUN 21 10:02

May 26, 1999



The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) We have chosen and combined the finest in whole food ingredients to bring you Folic Acid B<sub>12</sub>, helping to maintain your heart and mind as well as offering many other significant benefits.\*
- (2) It gives your body what it needs to keep your heart healthy, your cells dividing at a normal rate, and significant protection from developing a neural tube defect during pregnancy.\*
- (3) Standard Process Folic Acid B<sub>12</sub> helps regulate your metabolism and makes you feel better.\*

These statements are made for a dietary supplement containing a proprietary blend of carrot (root), calcium lactate, porcine stomach parenchyma, defatted wheat (germ), bovine spleen, ovine spleen, bovine adrenal Cytosol™ extract, oat flour, and ascorbic acid. Other ingredients include honey, cellulose, folic acid, and cyanocobalamin. The name of the product is Folic Acid-B<sub>12</sub>.

97S-0162

Also see docket 97S-0163

LET 3771



The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

